DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUN 13 2003

Jonathon W. Emord, Esq.
Emord and Associates, P.C.
5282 Lyngate Court
Burke, VA 22015

Re: Health Claim Petition: Glucosamine and Chondroitin Sulfate, and (1) Osteoarthitiris; (2) Osteoarthritis-related joint pain, tenderness and swelling; (3) joint degeneration; and (4) cartilage deterioration –Tracking No. 3A00001

Dear Mr. Emord:

This letter acknowledges receipt on May 29, 2003 by the Food and Drug Administration (FDA) of the petition you submitted, on behalf of Weider Nutrition International, Inc., pursuant to Section 403(r)(5)(D) of the Federal Food Drug and Cosmetic Act (FFD&C Act)(21 U.S.C. § 343(r)(5)(D)). The petition requests FDA authorization of 12 health claims for use on the labels and labeling of dietary supplements, for the relationships between the consumption of glucosamine and/or chondroitin sulfate and reduction in the risk of: osteoarthritis; osteoarthritis-related joint pain, joint tenderness, and joint swelling; joint degeneration; and cartilage deterioration.

This petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C Act and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 100-day period, which ends on September 6, 2003, or by a lack of action by FDA within the initial100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

In our preliminary review of your petition, we noticed that your petition contains several deviations from the petition format specified in 21 CFR 101.70(f). For example, the introductory paragraph in your petition does not follow the language specified in the regulation (although it does contain the information requested). The regulation specifies attachment section headings labeled A. B. C.., whereas your petition labeled all sections (including the unlettered introduction) with roman numerals. Some of the section headings in the petition varied from the headings specified in 101.70(f). In addition, 21 CFR 101.70(g) specifies that data under several letter headings (noted above) should be

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submitted on separate pages, suitably identified. Your section IV through VIII did not start on separate pages. Correct format facilitates the FDA review of petitions. We request that your future petitions follow the specified format.

Please feel free to contact me at (301) 436-1461 if you have questions concerning this petition.

Sincerely yours,

Tomoko Shimakawa

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